

Study Number: MOG08002B
Test Type: MOG
Route: Dosing in Feed
Species/Strain: Rat/Sprague-Dawley

PA08R: Statistical Analysis of Neoplastic Lesions with Litter Incidence

Test Compound: Bisphenol AF
CAS Number: 1478-61-1

Date Report Requested: 03/20/2020
Time Report Requested: 12:03:36
Lab: RTI

C Number:

MOG08002B

Study Gender:

Both

PWG Approval Date

See web page for date of PWG Approval

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	F0 Female			
	Treatment Groups (ppm)			
	0	338	1125	3750
Disposition Summary				
Animals Initially In Study	35	35	35	35
Early Deaths				
Scheduled Deaths				
Scheduled sacrifice, terminal (GD 18 - 24, LD 0 - 28, SD 24 - 27)	35	35	35	35
Number of Animals Examined	3	2		2
ALIMENTARY SYSTEM				
LIVER	(2)	(2)	(0)	(0)
CARDIOVASCULAR SYSTEM				
None				
ENDOCRINE SYSTEM				
None				
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
OVARY	(3)	(0)	(0)	(0)
UTERUS	(0)	(0)	(0)	(2)
HEMATOLYMPHOID SYSTEM				
None				
INTEGUMENTARY SYSTEM				
None				
MUSCULOSKELETAL SYSTEM				
None				

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F0 Female

Treatment Groups (ppm)

	0	338	1125	3750
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NERVOUS SYSTEM

None

RESPIRATORY SYSTEM

None

SPECIAL SENSES SYSTEM

None

URINARY SYSTEM

None

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F1 Male : Subchronic Male

	Treatment Groups (ppm)			
	0	338	1125	3750
Disposition Summary				
Animals Initially In Study	10	10	10	10
Early Deaths				
Scheduled Deaths				
Scheduled sacrifice, terminal (PND 115 - 119)	10	10	10	10
Number of Animals Examined	10	10	10	10
Total number litters	10	10	10	10
ALIMENTARY SYSTEM				
LIVER	(10)	(0)	(2)	(10)
PANCREAS	(10)	(0)	(0)	(10)
CARDIOVASCULAR SYSTEM				
HEART	(10)	(0)	(0)	(10)
ENDOCRINE SYSTEM				
None				
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
EPIDIDYMIS	(10)	(10)	(10)	(10)
PENIS	(2)	(0)	(0)	(1)
PREPUTIAL GLAND	(10)	(10)	(10)	(10)
PROSTATE GLAND	(10)	(10)	(10)	(10)
SEMINAL VESICLE	(10)	(10)	(10)	(10)
TESTIS	(10)	(10)	(10)	(10)

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F1 Female : Subchronic Females

	Treatment Groups (ppm)			
	0	338	1125	3750
Disposition Summary				
Animals Initially In Study	10	10	10	10
Early Deaths				
Scheduled Deaths				
Scheduled sacrifice, terminal (PND 116 - 120)	10	10	10	10
Number of Animals Examined	10	10	10	10
Total number litters	10	10	10	10
ALIMENTARY SYSTEM				
INTESTINE, RECTUM	(10)	(0)	(0)	(10)
LIVER	(10)	(1)	(0)	(10)
PANCREAS	(10)	(0)	(0)	(10)
CARDIOVASCULAR SYSTEM				
HEART	(10)	(0)	(0)	(10)
ENDOCRINE SYSTEM				
None				
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
CLITORAL GLAND	(10)	(1)	(0)	(10)
OVARY	(10)	(10)	(10)	(10)
UTERUS	(10)	(10)	(10)	(10)
VAGINA	(10)	(10)	(10)	(10)
HEMATOLYMPHOID SYSTEM				
None				

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F1 Male : Prenatal Males

	Treatment Groups (ppm)			
	0	338	1125	3750
Disposition Summary				
Animals Initially In Study	22	21	22	20
Early Deaths				
Scheduled Deaths				
Scheduled sacrifice, terminal (PND 119 - 121)	22	21	22	20
Number of Animals Examined	7	3	2	20
Total number litters	7	3	2	20
ALIMENTARY SYSTEM				
INTESTINE, COLON	(2)	(1)	(0)	(0)
CARDIOVASCULAR SYSTEM				
None				
ENDOCRINE SYSTEM				
None				
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
COWPERS GLAND	(2)	(0)	(0)	(12)
EPIDIDYMIS	(3)	(0)	(0)	(1)
LEVATOR ANI PLUS BULBOCAVERNOSUS MUSCLE	(2)	(0)	(1)	(18)
PREPUTIAL GLAND	(7)	(2)	(0)	(1)
PROSTATE GLAND	(2)	(0)	(0)	(18)
SEMINAL VESICLE	(2)	(1)	(1)	(19)
TESTIS	(3)	(0)	(0)	(1)

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F1 Female : Prenatal Females

	Treatment Groups (ppm)			
	0	338	1125	3750
Disposition Summary				
Animals Initially In Study	22	21	22	20
Early Deaths				
Euthanized, moribund	1			
Unscheduled Sacrifice				1
Scheduled Deaths				
Scheduled sacrifice, terminal (GD 21, LD 0, PND 125 - 129)	21	21	22	19
Number of Animals Examined	3		1	19
Total number litters	3		1	19
ALIMENTARY SYSTEM				
None				
CARDIOVASCULAR SYSTEM				
None				
ENDOCRINE SYSTEM				
None				
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
OVARY	(2)	(0)	(1)	(19)
UTERUS	(0)	(0)	(1)	(19)
HEMATOLYMPHOID SYSTEM				
None				
INTEGUMENTARY SYSTEM				
None				

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F1 Male : Fertility Males

	Treatment Groups (ppm)			
	0	338	1125	3750
Disposition Summary				
Animals Initially In Study	22	24	21	20
Early Deaths				
Found Dead		1		
Scheduled Deaths				
Scheduled sacrifice, terminal (PND 152 - 154)	22	23	21	20
Number of Animals Examined	22	24	21	20
Total number litters	22	24	21	20
ALIMENTARY SYSTEM				
LIVER	(2)	(1)	(0)	(0)
LEUKEMIA; MALIGNANT		1 (100%) [1]		
CARDIOVASCULAR SYSTEM				
None				
ENDOCRINE SYSTEM				
None				
GENERAL BODY SYSTEM				
None				

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F1 Male : Fertility Males

	Treatment Groups (ppm)			
	0	338	1125	3750
GENITAL SYSTEM				
COAGULATING GLAND	(22)	(24)	(21)	(20)
COWPERS GLAND	(22)	(24)	(21)	(18)
EPIDIDYMIS	(22)	(24)	(21)	(20)
LEVATOR ANI PLUS BULBOCAVERNOSUS MUSCLE	(22)	(24)	(21)	(20)
PENIS, GLANS	(0)	(0)	(0)	(1)
PREPUTIAL GLAND	(22)	(24)	(21)	(20)
PROSTATE GLAND	(22)	(24)	(21)	(20)
SEMINAL VESICLE	(22)	(24)	(21)	(20)
TESTIS	(22)	(24)	(21)	(20)
HEMATOLYMPHOID SYSTEM				
SPLEEN	(0)	(1)	(0)	(0)
LEUKEMIA		1 (100%) [1]		
INTEGUMENTARY SYSTEM				
None				
MUSCULOSKELETAL SYSTEM				
None				
NERVOUS SYSTEM				
None				
RESPIRATORY SYSTEM				
None				
SPECIAL SENSES SYSTEM				
None				

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F1 Male : Fertility Males

Treatment Groups (ppm)

0

338

1125

3750

URINARY SYSTEM

None

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F1 Female : Fertility Females

	Treatment Groups (ppm)			
	0	338	1125	3750
Disposition Summary				
Animals Initially In Study	22	24	21	20
Early Deaths				
Unscheduled Sacrifice				1
Scheduled Deaths				
Scheduled sacrifice, terminal (GD 46 - 50, LD 26 - 28, PND 158 - 162)	22	24	21	19
Number of Animals Examined	22	24	21	20
Total number litters	22	24	21	20

ALIMENTARY SYSTEM

None

CARDIOVASCULAR SYSTEM

None

ENDOCRINE SYSTEM

None

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

CERVIX	(22)	(24)	(21)	(20)
OVARY	(22)	(24)	(21)	(20)
UTERUS	(22)	(24)	(21)	(20)
VAGINA	(22)	(24)	(21)	(20)

HEMATOLYMPHOID SYSTEM

None

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F1 Male : F1 Extra Males

	Treatment Groups (ppm)			
	0	338	1125	3750
Disposition Summary				
Animals Initially In Study	21	46	46	40
Early Deaths				
Scheduled Deaths				
Scheduled sacrifice, terminal (PND 28)	21	46	46	40
Number of Animals Examined	3		8	20
Total number litters	2		5	9

ALIMENTARY SYSTEM

None

CARDIOVASCULAR SYSTEM

None

ENDOCRINE SYSTEM

None

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

EPIDIDYMIS	(2)	(0)	(8)	(17)
TESTIS	(2)	(0)	(8)	(20)

HEMATOLYMPHOID SYSTEM

None

INTEGUMENTARY SYSTEM

None

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F1 Male : F1 Extra Males

Treatment Groups (ppm)

0 338 1125 3750

MUSCULOSKELETAL SYSTEM

None

NERVOUS SYSTEM

None

RESPIRATORY SYSTEM

None

SPECIAL SENSES SYSTEM

None

URINARY SYSTEM

KIDNEY

(2) (0) (0) (0)

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F1 Female : F1 Extra Females

	Treatment Groups (ppm)			
	0	338	1125	3750
Disposition Summary				
Animals Initially In Study	45	29	48	17
Early Deaths				
Scheduled Deaths				
Scheduled sacrifice, terminal (PND 28)	45	29	48	17
Number of Animals Examined	1			
Total number litters	1			

ALIMENTARY SYSTEM

None

CARDIOVASCULAR SYSTEM

None

ENDOCRINE SYSTEM

None

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

None

HEMATOLYMPHOID SYSTEM

None

INTEGUMENTARY SYSTEM

None

MUSCULOSKELETAL SYSTEM

None

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F1 Male : PND28 Bio&MGWM Male

	Treatment Groups (ppm)			
	0	338	1125	3750
Disposition Summary				
Animals Initially In Study	12	12	12	12
Early Deaths				
Scheduled Deaths				
Scheduled sacrifice, terminal (PND 28)	12	12	12	12
Number of Animals Examined			1	3
Total number litters			1	3

ALIMENTARY SYSTEM

None

CARDIOVASCULAR SYSTEM

None

ENDOCRINE SYSTEM

None

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

EPIDIDYMIS	(0)	(0)	(0)	(3)
TESTIS	(0)	(0)	(1)	(3)

HEMATOLYMPHOID SYSTEM

None

INTEGUMENTARY SYSTEM

None

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F1 Male : PND28 Bio&MGWM Male

Treatment Groups (ppm)

0

338

1125

3750

MUSCULOSKELETAL SYSTEM

None

NERVOUS SYSTEM

None

RESPIRATORY SYSTEM

None

SPECIAL SENSES SYSTEM

None

URINARY SYSTEM

None

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F1 Female : Bio&MGWM @ VO

	Treatment Groups (ppm)			
	0	338	1125	3750
Disposition Summary				
Animals Initially In Study	12	12	12	12
Early Deaths				
Unscheduled Sacrifice				1
Scheduled Deaths				
Scheduled sacrifice, terminal (PND 26 - 39)	12	12	12	11
Number of Animals Examined	12	12	12	12
Total number litters	12	11	9	12

ALIMENTARY SYSTEM

None

CARDIOVASCULAR SYSTEM

None

ENDOCRINE SYSTEM

None

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

OVARY	(12)	(12)	(12)	(12)
OVIDUCT	(0)	(0)	(0)	(1)
UTERUS	(2)	(0)	(0)	(1)
VAGINA	(2)	(0)	(0)	(1)

HEMATOLYMPHOID SYSTEM

None

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F1 Female : Bio&MGWM @ VO

Treatment Groups (ppm)

0 338 1125 3750

INTEGUMENTARY SYSTEM

None

MUSCULOSKELETAL SYSTEM

None

NERVOUS SYSTEM

None

RESPIRATORY SYSTEM

None

SPECIAL SENSES SYSTEM

None

URINARY SYSTEM

None

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LEGEND

Number of animals examined for each tissue shown in parentheses. If none of the animals examined have the specific lesion then there is a blank for that dose group for that specific lesion. The exception to this is if statistical significance is found for a lesion and the control group has no animals with the lesion then a 0 is included for the control group on the table for that lesion.

Number of animals with observation reported with percent incidence in parentheses

Number of litters with observations shown in square brackets for F1 and F2 animals. F1 litter incidence based on the number of F0 dams; F2 litter incidence based on number of F1 dams.

Trend p-values are reported only for those organs that were fully examined in the control group plus two or more other dose groups. For organs that were fully examined in just the control and one other dose group, only the pairwise p-values are reported.

All trend and pairwise p-values are reported as one-sided.

Non-pregnant females from the F0 and F1 generations are included in the analysis.

Statistical significance for the control group indicates a significant trend test

Statistical significance for a treatment group indicates a significant pairwise test compared to the vehicle control group

Statistical analysis performed by Cochran-Armitage test with poly-3 adjustment for both trend and pairwise tests for the F1 Fertility and F1 Subchronic animals.

* Statistically significant at $P \leq 0.05$

** Statistically significant at $P \leq 0.01$

**** END OF REPORT ****